GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4787
ANSWERED ON:23.04.2003
SCHEDULE Y OF DRUGS AND COSMETIC ACT
BALIRAM

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Schedule Y of Drugs & Cosmetic Act is under revision;

(b) if so, the details thereof alongwith the members of the committee set up in this regard; and

(c) the time by which recommendations by them are likely to be submitted in this regared?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a): Yes, Sir.

(b): Schedule Y of Drugs and Cosmetic rules lays down the requirements and guidelines on clinical trial for import and manufacture of new drugs. It was incorporated in 1988.

In order to update the requirements under Schedule Y to meet present requirements and keeping in view the potential which the country possess in the field of clinical research, the Drug Technical Advisory Board agreed to undertake the review of Schedule Y.

The review of this Schedule has been done in consultation with a number of experts including Dr. Nilima Kshirsagar, Dean KEM Hospital Mumbai; Dr. B.N. Dhawan, Ex-Director, CDRI Lucknow, Dr. J.N. Pandey, HOD Medicine AIIMS, Dr. R.C Srimal, Scient ITRC, Dr. Y.K. Gupta Deptt. ofPharmacology, AIIMS, Dr. S.D. Seth, Scientist, ICMR, Dr. Shankar Narayana, Dr. Sudhir Srivastava CDRI, Lucknow, and Dr. N.K Ganguly, DG, ICMR.

(c): The recommendations in respect of changes to be made in Schedule Y have been received.